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| EXAMINER | |
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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/021,622
Filing Date: December 12, 2001
Appellant(s): LAESEKE ET AL.



Keith M. Baxter
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed August 20, 2007 appealing from the Office action mailed May 17, 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 6,261,242 | ROBERTS et al | 7-2001 |
| 5,122,137 | LENNOX | 6-1992 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al (6,261,242 B1).

Roberts et al teach a biopsy sampler with a means for cauterizing the biopsy site after the biopsy is taken (see Figures 4a-4c). The sampler includes an introducer shaft (50) that is a hollow tube that is sized for insertion into the patient along an insertion path to locate a first end of the tube at the biopsy site. The first end of the shaft includes an electrically conductive surface (22) on a conductive stylet having a first end supported by the shaft that is adapted to be exposed to tissue and communicates by means of an insulated conductor (28)(see Column 4, lines 46-48) with a radio frequency cauterizing electrical source (see Column 4, lines 40-41). A large area electrode is adapted to contact the patient without production of cauterization temperatures to complete a circuit when a monopolar electrode is used (see Column 6, lines 38-46). A biopsy needle (14)(see Column 6, lines 51-52) including a sampling means (30) is fit in the introducer shaft to be guided thereby.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al (6,261,242 B1) in view of Lennox (5,122,137).

Roberts et al teach a biopsy sampler with a means for cauterizing the biopsy site after the biopsy is taken. The sampler includes an introducer shaft (12) that is a hollow tube that is sized for insertion into the patient along an insertion path to locate a first end of the tube at a biopsy site. The first end of the tube includes an electrically conductive surface (22) that is adapted to be exposed to tissue that communicates by means of an insulated conductor (28)(see Column 4, lines 46-48) with a radio frequency cauterizing electrical source (see Column 4, lines 40-41). A large area electrode is adapted to contact the patient without production of cauterization temperatures to complete a circuit when the monopolar electrode is used (see Column 6, lines 38-46). A biopsy needle (14)(see Column 6, lines 51-52) including a sampling means (30) is fit in the introducer shaft to be guided thereby. After a biopsy sample is taken using the biopsy needle, the electrically conductive surface is activated to cauterize the biopsy site. The electrically conductive surface may be disposed on a stylet interfitted within the shaft (see Figure 8b). Roberts et al teach all of the limitations of the claims except that the conductive

surface is formed by a conductive stylet with a rounded tip and that a temperature sensor is disposed on the electrically conductive surface.

Lennox teaches a medical device for temperature controlled RF coagulation and cauterization of tissue. The device includes a conductive stylet (see Figures 1-6 and 9) having an insulated section (39) and an exposed, distal electrically conductive surface (28,35). A large area electrode (8) is adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the cauterizing and coagulating electrical source with the electrically conductive surface through the patient. A temperature sensor (29,36) is disposed at the electrically conductive surface (28,35) in order to provide an indirect means of measuring and controlling the temperature of the tissue surrounding the electrode, so as to prevent excessive tissue damage.

It would have been obvious to one of ordinary skill in the art at the time the Applicant's invention was made to withdraw a biopsy needle from an introducer shaft similar to that of Roberts et al after a biopsy is taken and then to insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and coagulate the biopsy tract as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage and leakage, while providing an indirect means measuring and controlling the temperature of the tissue surrounding the electrically conductive surface, so as to prevent excessive tissue damage.

**(10) Response to Argument**

Regarding the 35 USC § 102 rejection using Roberts et al:

The Applicants argue that Roberts et al fail to teach a means of obtaining a biopsy that is performed percutaneously. Based on the current claim language, the introducer shaft merely has to be "sized for percutaneous insertion". The device of Roberts et al can be sized for percutaneous insertion since the device can be used to gain access to the biliary tree (the bile ducts) of the patient. See Column 1, lines 13-16, where Roberts et al disclose endoscope biopsy systems for gaining access to the biliary tree of a patient. The bile duct is a vessel that is far smaller in diameter that that of the small intestine. In order to gain access to the bile duct, the overall diameter of the device, including the introducer shaft, would have to be inherently small enough. Due to the fact that the endoscope system can be sized to fit into smaller vessels (bile ducts), the endoscope system of Roberts et al disclose a system that can be sized for percutaneous insertion into the patient.

The Applicants further argue Roberts et al fail to disclose a stylet. However, based on the current claim language and the broadest interpretation of a stylet as defined by Merriam-Webster Online dictionary, Roberts et al do in fact disclose a stylet. As defined be Merriam-Webster Online dictionary, a stylet is a "slender medical probe" or "a thin wire inserted into a catheter to maintain rigidity or into a hollow needle to maintain patency". Based on the Merriam-Webster Online dictionary definition of a stylet, the stylet does not necessarily have to be a pointed object that is capable of piercing the skin. Therefore, the element (12) in Figure 4a of Roberts et al constitutes a stylet.

The Applicants also argue that Roberts et al fail to teach a "biopsy needle assembly", and there is "no structure in Rogers [Roberts et al] that would be considered a biopsy needle". The Examiner would like to point out Column 6, lines 51-52, where Roberts et al clearly discloses the use of a needle to assist in resecting tissue samples. Therefore, by utilizing the disclosed needle in Column 6, lines 51-52 of Roberts et al in conjunction with the introducer sheath and other disclosed elements, would inherently create a "biopsy needle assembly".

The Applicants also argue that the introducer shaft, as disclosed by Roberts et al, fail to teach, "an electrically conductive surface adapted to be exposed to tissue". Based on the current claim language, the electrically conductive surface does not necessarily have to be disposed directly on the introducer shaft itself, but instead as a conductive surface on an element that is slidably disposed within the introducer shaft. The slidable element with the electrically conductive surface can be exposed to tissue when the conductive element is advanced distally of the introducer shaft. Therefore, Roberts et al discloses this element, as shown in Figure 4a.

The Applicants further argue that there is no insertion path for cauterization in Roberts et al. The "insertion path" in Roberts et al is that of the colon. The current claim language does not disclose the cauterization of the entire insertion path of the biopsy assembly, but instead can be interpreted as cauterizing the biopsy site at a particular location along the insertion path. Roberts et al disclose the removal of a biopsy sample and then cauterizing the biopsy site to prevent blood loss. Therefore, Roberts et al disclose the elements of Claim 5, as currently written.

Regarding the 35 USC § 103 rejection of Roberts et al and Lennox:

The Applicants argue that Roberts et al fail to disclose the percutaneous insertion of the device, and the cauterization of the insertion path. See the above arguments with respect to the current claim language and the disclosure of the claimed elements in Roberts et al.

The Applicants further argue that there is no motivation to combine Roberts et al with Lennox "to insert another unnecessary electrode device". As disclosed in the above rejection, "Roberts et al teach all of the limitations of the claims except that the conductive surface is formed by a conductive stylet with a rounded tip and that a temperature sensor is disposed on the electrically conductive surface." Therefore, Lennox remedies the deficiencies of the disclosure of Roberts et al. Furthermore, the Applicants argue that Roberts et al teaches away from the insertion of another device into the introducer shaft after the biopsy has been taken to cauterize the site. Column 1, lines 19-29 in Roberts et al clearly disclose the procedure for taking a biopsy and then removing the tissue sample before the insertion of a cauterizing element to cauterize the biopsy site. Therefore, Roberts et al provide the motivation to obtain a biopsy, remove the biopsy from the introducer shaft and introduce a cauterizing element, such as the element of Lennox, in order to cauterize the biopsy site.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Brian Szmal

Conferees:

Max Hindenburg

Thomas Barrett